

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0681086	(X3) Date Survey Completed 03/27/2019
Name of Provider or Supplier St Bernards Physician Clinics, Inc	Street Address, City, State 415 East Matthews Avenue, Jonesboro, AR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D6013	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;</p> <p>This STANDARD is not met as evidenced by: . Through a review of the new instrument validation documentation for the CDS Medonic M Series Hematology Analyzer, lack of documentation, as well as interviews with staff, it was determined the Laboratory Director failed to approve validation procedures to ensure they are adequate to determine the accuracy, precision, and other pertinent performance characteristics as evidenced by: A. A review of the validation documentation for the CDS Medonic M Series Hematology Analyzer dated 11/01/2017 revealed the verification procedures were not approved or signed by the Laboratory Director. B. In an interview on 03/27/2019 at 1030, technical consultant (as listed on CMS form 209) confirmed the validation for the CDS Medonic Hematology Analyzer were not approved or signed by the Laboratory Director.</p>